

CBI SUBSTANTIATION

General filing

This Document Contains CBI: Yes ☒ NO ☐

Technical Contact:

Technical Contact Phone Number:

Submission number (if known):

Submitting Company Name:

Information element(s) claimed as CBI *: Please identify the appropriate information element(s) that you are substantiating from the list below. For any information element that is not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter, it shall be determined that you have waived your CBI claim, pursuant to 40 C.F.R. § 2.205(d).

You are responsible for substantiating each information element claimed as CBI. If a single substantiation response applies for all information claimed as CBI, you should indicate this in your substantiation response. If different substantiation responses are necessary to support CBI claims for different information types, you should provide separate substantiation responses for each information type, clearly identifying the information for which each substantiation applies in the free text boxes (e.g. Question B) or in the additional information box at the end of this form.

☒ Submitter

☐ Export Date

☒ Chemical

☐ Country

☐ Volume

☐ Release

☐ Use

☒ Site

☐ Plant Site

☐ Mixture

☐ Process

☐ Financial

☐ Properties

☐ Privacy

☐ Exposure

☐ Report/Study Title

☐ Envir-Release

☐ Report Study Information

☐ **Other information elements claimed as CBI** (Please list any other CBI claim or any TSCA Section 14(c)(2) assertion not listed above. In some cases, it may be appropriate to group the information into a class of information rather than responding to each item claimed as CBI. If you are asserting a category of information, please identify all information elements within that category):

**The generic template data elements and their descriptions were sourced from the Office of Pollution Prevention and Toxics' Confidential Business Information Tracking System (CBITS), a legacy Oracle database, and EPA Form No. 7710-58, "TSCA Health and Safety Study Coversheet".*

I. REQUIRED FOR ANY IDENTIFIED CBI CLAIM

A. Do you believe that any information element claimed as CBI is exempt from substantiation pursuant to TSCA section 14(c)(2)¹ ?

☒ Yes

☐ No

If you answered yes, you must identify the specific information element(s), provide the specific exemption(s) and answer no further questions. For any information element that is not exempt, please respond to all of the questions below.

<p>If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.</p>									
<p>The submission includes information about chemical identity of the PMN substance, which has not yet been offered for commerce. Thus, the information named above is exempt from substantiation pursuant to TSCA Section 14(c)(2)(G)</p>									
<p>B. Will disclosure of any information element claimed as CBI likely result in substantial harm to your business's competitive position?</p> <p><i>(If you answered yes, please describe with specificity the substantial harmful effects that would result to your competitive position if the CBI information element is made available to the public.)</i></p> <p><i>If you are claiming multiple information elements, please make sure to provide information for EACH element you identified above. If a single substantiation response applies for all information claimed as CBI, you should indicate this in your substantiation response.</i></p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>								
<p>As stated in the PMN, the connection between the PMN substance, the company [REDACTED], and the specific individual doing the registration [REDACTED] is not a public knowledge. The disclosure of this connection to the public will cause substantial harm to [REDACTED], because competitors will not only know about the new product, but also will be able to know where the company's research is directed.</p>									
<p>C. To the extent your business has disclosed any information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.</p> <table border="0"> <tr> <td>1. Non-disclosure agreement required prior to access.</td> <td><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> <tr> <td>2. Access is limited to individuals with a need-to-know</td> <td><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> <tr> <td>3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.).</td> <td><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> <tr> <td>4. Other internal control measure(s). <i>(If yes please explain below.)</i> Click or tap here to enter text.</td> <td><input type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> </table>		1. Non-disclosure agreement required prior to access.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2. Access is limited to individuals with a need-to-know	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.).	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	4. Other internal control measure(s). <i>(If yes please explain below.)</i> Click or tap here to enter text.	<input type="checkbox"/> Yes <input type="checkbox"/> No
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<p>D. Does any of the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p> <p>Click or tap here to enter text.</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>								
<p>E. Does any of the information you are claiming as CBI contain (a) trade secret(s)² ?</p> <p><i>(If you answered yes, please explain the reason for your belief and attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).)</i></p> <p>Click or tap here to enter text.</p>									

<p>F. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(B)³), then please indicate the number of years (between 1-10 years) or specific date of which the claim is withdrawn⁴?</p> <p>Click or tap here to enter text.</p>	
<p>G. Has the EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?</p> <p><i>(If you answered yes, please explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.)</i></p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p>
<p>Not to our knowledge</p>	
<p>Additional comments:</p>	

<p>II. REQUIRED ONLY FOR CHEMICAL IDENTITY CBI CLAIMS</p>	
<p>A. Are you claiming a specific chemical identity as CBI?</p> <p><i>(If you answered yes, please respond to questions below. If you answered no, please leave all questions below blank)</i></p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>B. Is the chemical substance (or mixture) on the confidential portion of TSCA Inventory?</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>C. Has the chemical substance (or mixture) been offered for commercial distribution?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p>
<p>D. Is the chemical substance known to be in US commerce?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	
<p>E. Would disclosure of the specific chemical name release confidential process information?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	
<p>The PMN substance is identified as a product by process</p>	
<p>F. In the case of a mixture, would disclosure of the chemical name disclose a portion of the mixture comprised by any of the chemical substances in the mixture?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>

Click or tap here to enter text.

Additional comments:

III.SUBSTANTIATION CERTIFICATION

Do you wish to claim this substantiation as CBI?

☒ Yes

TSCA section 14(c) requires that persons asserting a CBI claim shall certify to the validity of the claims. By the marking of a yes, you are certifying to the truth of the below statements.

☐ No

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- (i) My company has taken reasonable measures to protect the confidentiality of the information;
- (ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
- (iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

¹ “TSCA Section 14(c)(2) states:

Information generally not subject to substantiation requirements

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

² “Trade secret” is defined as “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.” Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

³ “TSCA section 14(e)(1)(B) States”

(B) in the case of information other than information described in subsection (c)(2)—

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- (i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or
 - (ii) if applicable before the expiration of such 10-year period, until such time as—
 - (I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or
 - (II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

⁴ Information with withdrawn CBI claims will be made available to the public without further notice.